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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------|
| 10/595,784   | 05/11/2006  | Michael K. Ohara     | PC25320A                 | 6672             |
| 28523 7590 12/14/2007<br>PFIZER INC.<br>PATENT DEPARTMENT, MS8260-1611<br>EASTERN POINT ROAD<br>GROTON, CT 06340 |             |                      | EXAMINER<br>ARCHIE, NINA |                  |
|  |             |                      | ART UNIT                 | PAPER NUMBER     |
|  |             |                      | 1645                     |                  |
|  |             |                      | MAIL DATE                | DELIVERY MODE    |
|  |             |                      | 12/14/2007               | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/595,784 | <b>Applicant(s)</b><br>OHARA ET AL. |  |
|                              | <b>Examiner</b><br>Nina A. Archie    | <b>Art Unit</b><br>1645             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 19-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**  
***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- keep together {
1. Group I: claims 19-21, 25-26, 28, 29-32, 33-36 drawn an adjuvant composition (Examiner interprets claim 18 as claim 36. Appropriate correction is advised).
  2. Group II: claims 22-24, 27 drawn to a human or non-human animal vaccine.
  3. Group III: claim 37, drawn to a vaccine administered either concurrently or co-administered with any of the antigens selected from any M. heamolytica with an adjuvant composition comprising any ceftiofur.
  4. Group IV: claims 38-40, drawn to a method for enhancing, increasing, upwardly modulating, diversifying or otherwise facilitating an immune response in an animal to an antigen.
  5. Group V: claim 41, drawn to a method of preventing a disease comprising the step of administering the adjuvant compositions or vaccines in claim 19.
  6. Group VI: claims 42-43 drawn to a method of preventing a disease comprising the step of administering the adjuvant compositions or vaccines in claim 22 and claim 24.
- keep together {

⇒ are rule 1.126 that the claims should be rewritten

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is adjuvant composition comprising one or more antimicrobial agents. The technical feature of Group 1 is anticipated by Sato Yukio et al 1999 Cellular Immunology Vol. 197 No. 2 pgs. 145-150. Sato Yukio et al teach an

adjuvant composition comprising one antimicrobial agent (14-member macrolide antibiotic) (see pgs. 145-150).

1. The technical feature of Group II is a human or non-human animal vaccine.
2. The technical feature of Group III is a vaccine administered either concurrently or co-administered with any of the antigens selected from any *M. hemolytica* with an adjuvant composition comprising any ceftiofur.
3. Group IV is a method of for enhancing, increasing, upwardly modulating, diversifying or otherwise facilitating an immune response in an animal to an antigen comprising administration of an antimicrobial agent to an animal
4. Group V is a method of use of Group I, an adjuvant composition.
5. Group VI is a method of use of Group II, a human or non-human animal vaccine.

Groups II-VI lacks unity with Group I because they do not have the same technical feature.

### **Election of Species**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If the Applicant elects Group IV, the Applicant is required to elect a combination of single individual species from Group IV listed below.

Species-antimicrobial agent;

Please select an antimicrobial agent from the group listed below.

Group of antimicrobial agents: penicillin v, cloxacillin, ampicillin sodium, ampicillin, amoxicillin, pivampicillin, carbenicillin, piperacillin, ticarcillin, ureidopenicillin, dzlocillin, temocillin, nafcillin, aminobenzylpenicillin, mecillinam, carboxypenicillin, cephradine, cephalothin, cephapirin, cefazolin, cephalixin, cefaclor, cephacline, cefadroxil, cefoperazone, cefoxitin, ceftiofur, ceftizoxime, ceftriaxone, cefuroxime,

cefquinome, cefotaxime, ceftriaxone, ceftazidime, clavulanate-amoxicillin, clavulanate-ticarcillin, sulbactam-ampicillin, piperacillin-tazobactam, amikacin, apramycin, gentamicin, kanamycin, neomycin, spectomycin, streptomycin, tobramycin, lincosamides, pleuromutilin, chloramphenicol, macrolides, lincosamides-lincosamine, clindamycin, pirlimycin, pleuromutilins - tiamulin, valnemulin, chloramphenicol, thiaphenicol, florfenicol, macrolides - erythromycin, tylosin, spiramycin, tiludicose, roxithromycin, azithromycin, clarithromycin, ketolide, tulathromycin, oxytetracycline, doxycycline, tetracycline, tetracycline hcl, oxytetracycline hcl, minocycline hcl, doxycycline hyclate, sulfamethazine, trisulfapyrimidine, sulfamethoxazole, sulfadimethoxine, sulfadiazine, sulfisoxazole, phthalylsulfathiazole, salicylazolsulfapyridine, silver sulfadiazine, enrofloxacin, orbifloxacin, difloxacin, danofloxacin, marbofloxacin, sarafloxacin, spectinomycin, imipenem, meropenem, cefotetan, cefprozil, loracarbef, cefdinir, cefpodoxime, cefibuten, ceftiofur, cefepime, dirithromycin, dictoxacillin, oxacillin, mezlocillin, nalidixic acid, ciprofloxacin, enoxacin, lomefloxacin, norfloxacin, ofloxacin, levofloxacin, sparfloxacin, alatrofloxacin, gatifloxacin, moxifloxacin, trimethoprim, aztreonam, quinupristin, fosfomycin, metronidazole, nitrofurantoin, rifampin, vancomycin, (2R,3 S,4R,5 R, 8R, 10R, 11 R, 12S, 13 S, 14R)- 13-(( 2,6-dideoxy-3-C-methyl- 3 -O-methyl-4-C-((propylamino)-methyl)-α-L-ribo-hexopyranosyl)oxy)-2-ethyl-3,4,10-trihydroxy- 3,5,8,10,12,14-hexamethyl- 11-((3,4,6-trideoxy- 3-(dimethylamino )-3-D-xylo- hexopyranosyl)oxy)- 1-oxa-6-azacyclopentadecan- 15 -one, and (3 R,6R,8R,9R, 10S, 11 S, 12R)- 11 ((2,6-dideoxy-3-C-methyl-3-O-methyl-4-C-((propylamino)methyl)-α-L-ribo-hexopyranosyl)oxy)- 2-(( 1R,2R)- 1,2-dihydroxy- 1 -methylbutyl)-8-hydroxy-3,6,8,10,12-pentamethyl-9-((3,4,6-trideoxy- 3-(dimethylamino)-[3-D-xylo-hexopyranosyl)oxy)- 1-oxa-4-azacyclotridecan-13-one.

Species-antigenic agent;

Please select an antigenic agent from the group listed below.

Group of antigenic agents: *Pasteurella multocida*, *Mannheimia haemolytica*, *Haemophilus somni*, and *Pasteurella haemolytica*.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Archie whose telephone number is 571-272-9938. The examiner can normally be reached on M-F 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Shannon Foley can be reached on 571-272-8975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Nina Archie  
Patent Examiner  
Art unit, 1645  
Remsen 3B31

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Nina Archie  
Patent Examiner  
Art unit, 1645  
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MARK NAVARRO  
PRIMARY EXAMINER